

JAN 25 2012

510(k) SUMMARY

XENON™ Pedicle Screw System
November 2011

Company: Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008
Direct: (760) 494-6770
Fax: (760) 431-0289

Contact Person: Cheryl Allen, Sr. Regulatory Affairs Submissions Specialist

Trade/Proprietary Name: XENON™ Pedicle Screw System

Common Name: Pedicle Screw Spinal Device

Classification Names: Pedicle Screw Spinal System

Device Classification: Class III per 21 CFR 888.3070

Product Code(s): NKB, MNI, MNH

Product Description:

The system is comprised of XENON standard polyaxial screws, hightop polyaxial screws, set screws, rods. The XENON polyaxial screw features a dual lead thread, 3 prong drive instrument interface and is self tapping. The polyaxial screws are offered in various diameters ranging from 4.5mm to 8.0mm and lengths ranging from 25mm and 80mm. The polyaxial screws range of motion is 50 degrees Medial/Lateral and 50 degrees Inferior/superior. The 5.5mm diameter rods are offered in lengths 35mm to 600mm. The rods are also offered in two profiles, straight and pre-contoured. The adjustable bridges are offered in 4 different sizes. The implants are manufactured from surgical grade titanium alloy (Ti6Al-4V).

Indications for Use:

The XENON Pedicle Screw System is intended for posterior, non-cervical pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion. It is intended to provide stabilization during the development of fusion utilizing autograft or allograft bone graft.

Substantial Equivalence:

Alphatec Spine has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the XENON Pedicle Screw System is substantial equivalent in the intended use, design materials, mechanical and functional characteristics compared to the predicate devices. The XENON Pedicle Screw System is substantially equivalent to the following predicate devices:

<u>Trade/Proprietary/Model Name</u>	<u>Manufacturer</u>	<u>510(k) No.</u>
Zodiac® 4.0 Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K071890
Zodiac® Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K100685
Apelo™ Pedicle Screw System	Atlas Spine, Inc.	K110842

Performance Data:

Mechanical static and dynamic testing was performed which provides reasonable assurance of safety and effectiveness for its intended use. Performance testing was performed per the recognized consensus standards and per the guidance document, Spinal 510(k)s- Guidance for Industry and FDA Staff. The following testing was performed per ASTM F1717:

- Dynamic Compression Bending
- Static Torsion
- Static Compression Bending

The testing demonstrated that XENON Pedicle Screw System is substantially equivalent to the predicate Zodiac® Polyaxial Spinal Fixation System device. It is similar in terms of general design, intended use, and technological characteristics to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

JAN 25 2012

Alphatec Spine, Inc.
% Ms. Cheryl Allen
5818 El Camino Real
Carlsbad, California 92008

Re: K111634

Trade/Device Name: XENON™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: January 18, 2012
Received: January 20, 2012

Dear Ms. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

Page 2 – Ms. Cheryl Allen

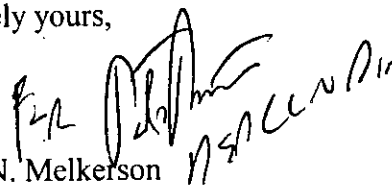
comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson

Director

Division of Surgical, Orthopedic
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: XENON™ Pedicle Screw System***Indications for Use:***

The XENON Pedicle Screw System is intended for posterior, non-cervical pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion. It is intended to provide stabilization during the development of fusion utilizing autograft or allograft bone graft.

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

A handwritten signature in black ink, appearing to be "J. [unclear]", is written over a horizontal line.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111634